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07/949,652 09/23/92 SIMONS

M M-1647-6C-US

EXAMINER

18N1/0113

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ART UNIT	PAPER NUMBER
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1807

DATE MAILED: 01/13/94

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 12/27/93 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter. Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892. 2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☒ Notice of Art Cited by Applicant, PTO-1449. 4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474. 6. ☒ Interview Summary

Part II SUMMARY OF ACTION

1. ☒ Claims 1-16, 21-27, 37, and 39-43 are pending in the application.
- Of the above, claims _____ are withdrawn from consideration.
2. ☒ Claims 17-20, 28-36 and 38 have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-16, 21-27, 37 and 39-43 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received
☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other _____

EXAMINER'S ACTION

MISCELLANEOUS

1. The finality of the prior Office action is hereby WITHDRAWN. Prosecution on the merits has been reopened.

2. Acknowledgement is made of the filing of the response and amendment of
5 December 27, 1993.

3. Claims 1-16, 21-34, 37, and 39-43 are currently pending. Said amendment has resulted in the cancellation of claims 17-20, 28-36, and 38

4. All rejections of claims 17-20, 35, 36, and 38 are hereby withdrawn as the cancellation of said claims has rendered moot any rejection of same.

10 **OBJECTIONS**

1. The specification is objected to in the following manner: It is noted that on repeated occasions reference to incorporated publications has been made, yet no direction is given to the pertinent pages of said references; *e. g.*, see pages 3-7 and 24. Applicants are required to amend the specification, clearly indicating what passages of
15 the cited and incorporated references are to be considered pertinent to the subject discussed. Support for such clarification of the prior art can be found in the December 15, 1992 publication of the U. S. Patent and Trademark Office Official Gazette, 1145 TMOG 361, first column where is stated in part:

20 Particular attention should be directed to specific portions of the referenced document where the subject matter being incorporated may be found.

2. The specification is objected to where in the first paragraph of the specification, the current status of related application(s) is not indicated.

In particular, application 07/398217, filed 08/25/89, went abandoned 05/25/90, and application 07/405499, filed 09/11/89, went abandoned 03/12/90.

3. The Abstract of the Disclosure is objected to because of the inclusion of legal phraseology (*exempli gratia*, comprises). Correction is required. See MPEP 608.01(b).

REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

5 "The specification shall contain a written description of the invention, and of
the manner and process of making and using it, in such full, clear, concise, and
exact terms as to enable any person skilled in the art to which it pertains, or
with which it is most nearly connected, to make and use the same and shall set
10 forth the best mode contemplated by the inventor of carrying out his
invention."

The specification is objected to under 35 U.S.C. § 112, first paragraph, as the specification, as originally filed, does not provide support for the invention as is now claimed.

15 Claims 1-16 are not supported by the original disclosure for "non-coding
regions". Acknowledgement is made of applicant's indication for support of said phrase
on page 4 of the preliminary amendment, filed September 23, 1992, wherein it is
indicated that support "is found in the Specification at page 10, lines 29-33 which
defines 'intron'."

20 In reviewing said page 10, lines 29-33, it is clearly evident that the use of the
term "non-coding" was being made in reference to an intron. The phrase does not
provide support for the use of "non-coding" regions in general. An intron and non-
coding regions are not mutually exclusive. While an intron can be considered as a non-
coding region, it is not to say that all non-coding regions are introns. Other examples
of non-coding regions are: (1) promoters; (2) terminal repeats; and (3) non-coding
25 regions between genes (an intron is limited to the non-coding region between exons of
a given gene, not that which occurs between genes). In reviewing the specification,
support for the use of 'intron' has been located and it readily apparent that the non-
coding region contemplated is that associated with introns, not that associated with
generic material in a general sense. Accordingly, the use of non-coding effectively

broadens the scope of the claims beyond that originally filed and supported by the specification.

Appropriate correction is required.

5 Claims 1-16 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, *id est* failing to provide an enabling disclosure.

10 The specification teaches the determination of the likelihood of a criminal suspect as being implicated in a crime and the parentage of a child wherein in both instances the RFLP pattern for HLA locus was analyzed. The specification does not provide sufficient enablement such that one of skill in the art would be able to detect at least one coding region allele of a multi-allelic genetic locus where the genomic DNA can be derived from virtually any source. In particular, the specification has not
15 provided guidance as to how one is to predetermine what types of primers (sequence length and composition) are to be used given the generic applicability of the claimed method to a variety of loci. This aspect is further complicated when one considers that a given locus may well be comprised of a cluster of alleles (*exempli gratia* the HLA Class II locus DQA1 is comprised of 8 alleles and the DPB locus is comprised of 24 alleles).

20 The specification is not enabling for the generation and use of primers that would be of sufficient length such that they permit the spanning of virtually any intronic sequence. To this end, applicant's attention is directed to the publication of Padgett *et alii*, where on page 1124, second paragraph, it is stated: "The length of introns in vertebrate genes ranges from approximately 50 to well over 10,000 bases
25 with no obvious periodicity." While this publication only makes reference to that encountered in vertebrates, the claimed method has sufficient breadth of scope so as to permit the inclusion of invertebrates as well as plants and fungi. Clearly, the specification has not provided sufficient guidance as to the application of the instantly

claimed method to "for detection of at least one coding region allele of a multi-allelic genetic locus" which entails the use of a "primer pair that spans a non-coding region sequence" where said non-coding region can be but is not limited to introns; see *supra*

5 Claims 1-13, 15, 16, 37, and 39-41 are rejected under 35 U.S.C. 112, first paragraph, for the reasons set forth in the objection to the specification.

REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

Claims 1-16, 26, 27, 37, and 39-43 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

W/d 10 Claim 7 is indefinite with respect to just what the phrase "genetic variation" is to entail.

W/d Claims 1-16 are all drawn to a method of detection, yet said claims fail to recite any detection step. Accordingly, said claims are indefinite for failing to recite sufficient method steps.

W/d 15 Claim 26 is drawn to "a method for determining whether DNA in a sample is from a particular individual", however, said claim fails to recite any method step which calls for such a determination. Accordingly, said claims are indefinite for failing to recite sufficient method steps.

20 Claims 27, 37, and 39-43 are also drawn to a method of determination, however, like that of claims 1-16 above, said claims fails to recite method steps for such "determining".

25 Claim 21, and claims 22-24 which depend therefrom, are confusing with respect to the phrase "primers being located in intervening sequence I and in intervening sequence III". How is a primer located in such a sequence? Perhaps applicant had intended to indicate that the primer would hybridize specifically to regions found in intervening sequences I and III.

Claims 22, 24, and 25 are confusing as it is not readily apparent where the method steps of said claims are to occur in the method steps of claim 21.


Claim 37, and claims 39-43 which depend therefrom, are incorrect as claim 37 fails to recite in the preamble a general description of of all the elements or steps of the claimed combination. See MPEP 608.01(m) and 37 C.F.R. §1.75.

REMARKS


No claim is allowed.

Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO FAX Center, located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 FAX Center number is (703) 308-4227.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Bradley L. Sisson whose telephone number is (703) 308-3978. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Bradley L. Sisson
Examiner

January 7, 1994


MARGARET PARR
SUPERVISORY PATENT EXAMINER
GROUP 1800